

REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment, claims 1-5, 14-33, 35-37 and 65-66 are pending. Claims 1 and 35-36 are amended, new claims 65-66 are added and claims 6-8, 34, 38-62 and 64 are canceled without disclaimer or prejudice to renewal.

Claim 1 is amended to set forth a topical delivery composition wherein the pH-adjusting agent is an acid or a base. Support is found, for example, on page 9, lines 14-18, and claim 34.

Claims 35-36 are amended to update their dependencies in view of the cancellation of claim 34.

New claim 65 incorporates the language of claims 1 and 2.

New claim 66 incorporates the language of claim 3.

Reconsideration is respectfully requested.

Restriction Requirement

Applicants confirm their election to prosecute the inventions of Group I, drawn to compositions comprising quick-breaking foaming agents, and the ratio of claim 15. As the following amendments and remarks place the application in condition for allowance, Applicants respectfully request that claims 10-12 be rejoined.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner's rejection of claim 38 under 35 U.S.C. § 112, second paragraph, is rendered moot by the cancellation of this claim.

Rejection under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1, 5 and 14-37 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Publication No. 2003/0118511 ("Jones").

As the Examiner knows, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference. M.P.E.P. § 2131.

This rejection is rendered moot by amending claim 1 to set forth that the pH adjusting agent is an acid or a base. In contrast, the foamable pharmaceutical compositions of Jones require a buffering agent (*see*, the abstract, paragraphs 0006-0007, and independent claim 1 of Jones). Jones clearly states that it has been found important to include a buffering agent in the composition to stabilize the active isomer of the corticosteroid active substance (*see*, paragraph 0007). Suitable buffering agents include an acid component and a base component (*see*, paragraph 0021). The present specification likewise distinguishes an acid or a base from a buffer, which comprises an acid component and a base component (*see*, paragraph 0042 on page 9, lines 13-23).

Because Jones does not teach or suggest each and every element of the claimed compositions, it can not properly anticipate them. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claims 2-4, 6 and 8 under 35 U.S.C. § 103(a) as allegedly obvious over Jones in view of U.S. Patent No. 2004/0043946 ("Popp").

As the Examiner knows, a *prima facie* case of obviousness requires that the cited references teach or suggest all of the claim limitations. M.P.E.P. § 2143.

Here as discussed above, and as the Examiner concedes, Jones does not teach each and every element of the claimed compositions because Jones's foamable pharmaceutical compositions require a buffering agent and only disclose a corticosteroid as an active agent. Popp does not cure the deficiencies of Jones, because Popp is not prior art under 35 U.S.C. § 103(a)/102(e).

In order to expedite prosecution of the present case and without commenting on the relevance of Popp, Applicants submit herewith a Rule 131 Declaration signed by co-inventors Albert Abram and Barry Hunt and its accompanying attachment, Exhibit A. Exhibit A includes sequential pages 58-63 from the laboratory notebook of Barry Hunt. The entries in Exhibit A were made before the September 3, 2002 priority date of Popp, but the actual date entries have been redacted. Exhibit A demonstrates that Applicants had conceived of and reduced to practice a topical delivery composition in a pressurized container comprising up to 15% of a pharmaceutically active compound, about 83%-97.9% of a quick-breaking foaming agent comprised of a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant, and about 2%-7% of a propellant (*i.e.*, P70) (*see*, page 58 of Exhibit A) before September 3, 2002. Exhibit A further demonstrates how Applicants adjusted the pH of the composition using an acid or a base (*see*, pages 58-63).

Applicants conception and reduction to practice of the claimed invention before the September 3, 2002 priority date removes the Popp publication as prior art. Therefore, because the combined disclosures of Jones and Popp do not teach or suggest each and every element of the claimed compositions, they can not render them obvious. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Appl. No. 10/763,379
Amdt. dated August 11, 2005
Reply to Office Action of May 12, 2005

PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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